Statement of
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"Status of the Efforts of the FDA and DEA in regulating Schedule II Prescription Painkillers, Specifically OxyContin® and Other Opioid Analgesics"

Chairman Miller, Congressman Lynch, and distinguished members of the Subcommittee, I appreciate your invitation to testify today on the status and efforts of the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) in regulating Schedule II painkillers, specifically OxyContin® and other opioid analgesics.

The Problem

The non-medical use of prescription drugs has become an increasingly widespread and serious problem in the United States. A new generation of high dose, extended release, opioid pain medications have taken the existing threat to a new level. The abuse and diversion statistics are alarming, and the increased popularity of these prescription drugs creates even greater challenges for the medical and law enforcement communities. While these new drugs have proven effective in the treatment of chronic pain, they also offer equally increased risks of abuse and diversion.

OxyContin®, Duragesic®, and other Schedule II opioids are examples of the type of prescription drug that is the highest risk for diversion. The potency, purity and quantity of their active ingredients make them stronger and more dangerous than ever, providing a greater temptation for addicts by offering a high potential for deliberate abuse by those seeking narcotic drugs. These powerful drugs provide strong incentives for diversion through new means, such as "rogue" Internet pharmacies, as well as older methods, like prescriptions written for profit.

Recent drug use surveys have highlighted the gravity of this problem. For example, the non-medical use of prescription drugs ranks second only to marijuana as the most prevalent category of drug abuse. According to the *Monitoring the Future Survey*, there has been a 24 percent increase in past year use of OxyContin® for all grades combined (8^{th}, 10^{th}, and 12^{th}) between 2002 and 2004. The 2004 *National Survey on Drug Use and Health* reported that the drug category with the largest number of recent initiates was non medical use of pain relievers, with an estimate of 2.4 million new initiates.

The DEA understands the importance of aggressive action in this area, and we are addressing OxyContin® diversion and abuse through our comprehensive *OxyContin® National Action Plan*. This plan focuses our enforcement and regulatory investigations on key points of OxyContin® diversion, such as unscrupulous or unethical medical professionals; forged or fraudulent prescriptions; pharmacy theft; and "doctor shoppers" (abusers who move from doctor to doctor seeking prescriptions). Since implementing the *National Action Plan* in April 2001, the DEA has initiated 720 OxyContin® investigations, which have resulted in 812 arrests (as of September 6, 2005).

Prescription drug abuse of opioid medications tends to be concentrated in certain areas of the country. As this committee is well aware, the Boston, Massachusetts, region is one of those areas. DEA investigations have shown that oxycodone products such as Percocet®, Roxicet® and OxyContin® are readily available in the state, and originate from a variety of sources. For instance, law enforcement has intercepted shipments of Oxycontin® that were diverted from legitimate distributors, including the diversion of express mail shipments into the greater Boston area. We have also seen well organized doctor shopping rings, the use of forged or altered prescriptions, and diversion from individuals' legitimate prescriptions.

The demand for diverted pharmaceuticals, particularly pain relievers such as OxyContin®, has fueled illicit organized distribution rings in New England. In November 2004, DEA agents arrested 18 members of an OxyContin® distribution ring who had obtained the drug in New Jersey and transported it to New England for distribution. Two of the members allegedly were associated with organized crime families. In July 2004, DEA agents and local law enforcement officers charged 13 individuals involved in an OxyContin® distribution ring operating in Gloucester, Peabody, and Danvers, Massachusetts. This group was involved in a conspiracy to distribute approximately 35,000 80-milligram OxyContin® tablets with a total street value of over $2 million. The major supplier for this group was a member of the Red Devils outlaw motorcycle gang.

Coordinating Regulatory Responsibilities

As the DEA fights against diversion and drug abuse both here in Boston and across the nation, the proper regulatory control of new pharmaceuticals is vital. Appropriate control mechanisms are particularly important given the strength of the new, extended release products coming on the market.

Currently, the DEA establishes and enforces three types of quotas for Schedule I and II substances. The three are: aggregate production quotas, manufacturing quotas and procurement quotas. The quota system ensures that there is an adequate and uninterrupted supply of controlled substances in Schedules I and II for legitimate medical and scientific needs, while placing limits on the total amount available in order to prevent

diversion. These quotas are established from research through marketing and extensive discussions with the industry that help the DEA establish the potential legitimate market for any new substance.

I would like to make special mention of Prescription Drug Monitoring Programs (PDMPs), which assist states in identifying diversion trends as they emerge. The DEA has strongly supported prescription monitoring programs. PDMPs collect prescription information electronically from pharmacies. The data collected is analyzed by state agencies or third parties and provided to state agencies to assist in the identification of "doctor shoppers" and over-prescribers. The effort often results successful law enforcement and regulatory investigations. In addition, the information collected and analyzed by a state PDMP may be used by doctors to assist in identifying patients whose drug usage is increasing and who may benefit from a referral to a pain specialist or to substance abuse treatment. It may also be used to assist pharmacists in providing appropriate pharmaceutical care.

The DEA's goal is to work with all interested parties to ensure that prescription data pertaining to controlled substances is collected in a cost-effective manner from the largest possible segment of dispensers, while protecting the confidentiality of the collected data and the legitimate practice of medicine. We believe state PDMPs will be able to reach their full potential as one tool in preventing the diversion of controlled substances from legitimate channels. Recently Federal oversight of PDMP's was transferred to the Department of Health and Human Services with the passage of the "National All Schedules Prescription Drug Reporting Act," which was signed into law by the President on August 11, 2005. The DEA looks forward to working with the Department of Health and Human Services as they take the lead on this effort.

National Drug Control Strategy

In addressing the growing problem of pharmaceutical drug abuse and diversion, the DEA, in collaboration with the Department of Justice, the Office of National Drug Control Policy, the FDA, and other law enforcement and community partners, has launched a comprehensive *Prescription Drug Strategy* to address all areas of concern and all sources of diversion. This *Prescription Drug Strategy* is a component of the *National Drug Control Strategy—Stopping Drug Use Before it Starts; Healing American's Drug Users: Getting Treatment Resources Where They Are Needed;* and *Disrupting the Market: Attacking the Economic Basis of the Drug Trade.*

The DEA supports the Strategy through its support of educational efforts by communities, schools, the media, and other organizations. Most recently the DEA launched an anti-drug website for teens, www.justthinktwice.com. This site provides young people with straightforward information on the consequences of drug use and trafficking, including health, social, legal, and international consequences. It will be continually updated to provide current information to teens and will be expanded and refined to reflect the needs of teens. We expect the site to be a valuable resource for

teens seeking information on drugs for their own education or for school research projects.

In addition, in early FY 2005, the DEA began working with its partners to develop public service announcements that will appear automatically during Internet prescription drug searches. These announcements are designed to alert consumers of the potential dangers and the illegality of purchasing controlled substances, particularly pharmaceuticals, over the Internet. Both AOL and Google have responded by instituting voluntary compliance measures and corporate commitments to taking affirmative steps to curtail the illicit sale of pharmaceuticals on their networks. The DEA also is meeting with the leading certifying medical boards, encouraging them to develop educational programs concerning the prescribing of controlled substances, especially high-dose opioids.

The DEA plays a vital role in implementing the second core tactic, *Healing American's Drug Users: Getting Treatment Resources Where They Are Needed*, by establishing quotas for controlled substances. Quotas provide for an adequate and uninterrupted supply of abuse treatment drugs, while limiting the amount available to potential diversion.

The DEA also issues registration identification numbers to treatment physicians with Substance Abuse and Mental Health Services Administration waivers. Under the Drug Abuse Treatment Act of 2000, the Controlled Substances Act (CSA) requirement for a separate Narcotic Treatment Program registration is waived for qualified practitioners to treat opioid addiction using FDA approved Schedule III-V controlled substances. Qualified practitioners are issued unique identification numbers that allow them to provide opioid addiction treatment from their offices. As of September 2, 2005, the DEA has registered 5,840 of these physicians throughout the United States. This registration represents a major effort to improve the quality and delivery of, and expand access to, addiction treatment.

The DEA has established the core tactic, *Disrupting the Market: Attacking the Economic Basis of the Drug Trade* as a priority of the Prescription Drug Strategy. We have increased the time dedicated to pharmaceutical investigations and continue to focus our drug enforcement efforts toward the most significant members of the drug supply chain. Enforcement efforts undertaken by the DEA are aimed at the economic base of drug traffickers; strong emphasis is placed on seizures of financial and other assets.

The DEA seeks to reduce the profitability of the drug trade and increase the costs of drugs to illicit consumers. In other words, the DEA seeks to inflict upon illicit drug business what every legal business fears: escalating costs, diminishing profits, and unreliable suppliers. The DEA's effort to stem the illegal sale of controlled pharmaceuticals has resulted in the dismantling of major organizations and the increasing seizure of assets. DEA Registrants found to be in violation of regulatory requirements under the CSA are subject to significant civil fines. Such civil remedies have proven to be a deterrent to potential violators.

Our work in pursuing these violators has been effective. On June 17, 2005, arrest warrants were issued charging 24 individuals from five states, including Massachusetts, with conspiracy to distribute Oxycodone and conspiracy to commit money laundering. These individuals allegedly were involved in a ring responsible for obtaining Oxycodone, primarily in the form of OxyContin®, in Florida and subsequently distributing the drug in New England. The ringleader allegedly sent money, in amounts of $4,000 to $78,000, in exchange for 500-plus-tablet quantities of OxyContin®. The ring had operated for several years and had obtained hundreds of OxyContin® tablets each week. The charges are a result of a 2½-year investigation involving various state and local law enforcement agencies, the DEA, and the Internal Revenue Service (IRS). This OxyContin® distribution ring is the third such ring dismantled in the New England area over the past year.

The DEA is applying a two-fold strategy in attacking the money laundering aspects of these investigations. In those cases involving illegal distribution via the Internet, credit card and electronic payments are being traced through the various processing layers to identify both the recipients and the final destination of the funds for subsequent seizure. In those investigations involving individual doctors and clinics issuing illegal prescriptions, more traditional financial investigative techniques are being employed to trace and seize their illicit profits.

Radio-Frequency Identification Technology

The subcommittee has expressed interest in Radio-Frequency Identification (RFID). RFID is an emerging technology, based on wirelessly exchanging information between a tagged object and a reader/writer. The benefits of RFID for drug manufacturers or distributors are improved tracking and control of inventory, production, shipping, and receiving.

The use of radio-frequency identification technology is more appropriate for case lots and commercial packages of bottled drugs. While properly placed detectors would alert if a bottle containing a chip were taken, the ease of emptying the commercial bottle and taking only the pills is evident. The overwhelming majority of pharmaceutical controlled substance seizures that the DEA encounters come in loose tablets, dispensed bottles, or plastic bags. The commercial container has been discarded long before the DEA sees the product. We also rarely see counterfeited versions of controlled substances.

The DEA does not regulate or require RFID under our existing security regulations. Still, we will continue to monitor and evaluate the usefulness of RFID technology as a potential deterrent to the diversion of legitimately produced pharmaceuticals at the dosage unit level.

New Approaches to Address Prescription Painkiller Addiction and Abuse

The DEA continues to develop new strategies to aggressively address addiction and abuse of controlled pharmaceutical painkillers. The newer enforcement approaches we have taken include: increasing Priority Target Investigations; creating Tactical Diversion Squads focused on prescription drug diversion at the retail level; developing a comprehensive enforcement and regulatory strategy to address the growing problem of illicit sales of pharmaceuticals on-line; and implementing a specialized training seminar for Assistant United States Attorneys that focuses on prosecution strategies for diversion cases.

In addition, we are taking an active role in educating the medical community and drug industry and providing prescription drug information, resources, and training to state and local government officials, community coalitions, educators, prevention organizations, students, and the general public. Other efforts include establishment of the DEA's international, toll-free 24-hour tip line number, 1-877-RXAbuse, the new teen website www.justthinktwice.com, prescription monitoring programs, public service announcement via the Internet, E-Commerce and E-Prescribing Initiatives, and Risk Management Plans.

Conclusion

The DEA is addressing OxyContin® and other opiod addiction on many fronts, from education to regulation and enforcement. We will continue to work with the FDA and other agencies to reduce the diversion and abuse of these drugs while ensuring that a sufficient supply exists to meet legitimate medical needs. The DEA is vigorously executing the core tactics of the 2005 National Drug Control Strategy, keeping u tp date with cutting-edge technologies, and actively seeking new, innovative approaches to prevent diversion of legitimate pharmaceuticals.

Thank you for your recognition of this important issue and the opportunity to testify here today. I will be happy to answer any questions you may have.